EC Certificate
Full Quality Assurance System

Certificate No.: EU1407403 Date: 2014-07-14

Order No.: 260253

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Manufacturer:	CP Medical, Inc. 803 NE 25th Ave Portland, OR 97232 USA
Device categorie(s):	MD 0102 and MD 0203
GMDN code:	33069 and 40808
Models:	Listed on the next page
Risk class as defined by the manufacturer:	IIb
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.
Date of audit:	2013-11-18
End of the validity:	2019-08-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

for Ragnar Stranger Christiansen
For Nemko AS

Nemko Norway
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803 NE 25th Ave
Portland, OR 97232
USA

Certificate History:

Revision	Description	Issue Date
0	Recertification	2014-07-14

The certificate referred to above, includes the following devices/models:

Device Category	Model Name	GMDN Code
MD 0203	Non-sterile Gold Markers: 202xxx; 206xxx; 208xxx; 210xxx; 211xxx; 212xxx; 218xxx Sterile Gold Markers: 202xxx-Sx; 206xxx-Sx; 208xxx-Sx; 210xxx-Sx; 211xxx-Sx; 212xxx-Sx; 218xxx-Sx	40808
MD 0102	Brachytherapy Needles, sterile: 0135-xx-xx; 97-10-xxx; CPPS-xxxxx; CPPS-xxxxx-x; CPPS-BT-xxxx; CPPS-BYT-xxxx; CPPS-MN-xxxx; CPPS-SQ-xxxx; CPPS-SQ-xxxxx; CPPS-SQ-xxxx-x; CPPS-SQ-xxxxx-x; CPPS-SQY-xxxx; CPPS-SQY-xxxxx; CPPS-SQY-xxxx-x; CPPS-SQY-xxxxx-x; CPPS-SQY-xxxxx-xx; FP-00xx; IAPS-1820x-x; RPLN-x; RPLN-x-x; RPLN-xx Brachytherapy Needles, non-sterile: CPPS-BT-xxxx-NS; CPPS-BTY-xxxx-NS; CPPS-SQ-xxxx-NS; CPPS-SQ-xxxxx-NS; CPPS-SQY-xxxx-NS; RPLN-x-NS; RPLN-xx-NS	33069

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MD 0102 and *MD 0203	Pre-Waxed Brachytherapy Needles with *Gold Markers: FN17-x; FN17-xx; FN17-xxx; FN17-xxxx; FN17-xx-x-xx; FN17-xxx-x; FN1730-xx; FNS17-x; FNS17-xx; FN18-x; FN18-x-xx; FN18-xx; FN-18-xx-x-xx; FN18-xxx-x; FN1812-x; FN1812-xx; FN18-20-S; FNS18-xx; FNS1812-x; 10xx, 20xx	33069 and *40808

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